

REMARKS

This paper is in response to the final official action dated June 19, 2007 (hereafter, "the official action"). This paper is timely-filed as it is accompanied by a petition for an extension of time and authorization to charge our deposit account no. 13-2855 in the amount of the requisite extension fee.

Claims 1-19 and 21-38 are currently pending. By the foregoing, claims 1, 4-6, 11, 15, and 25-38 have been amended to address matters of form. Additionally, independent claims 1 and 25 have been amended to more clearly recite "evaporating essentially all of the water immiscible organic solvent by sonicating the system/emulsion," respectively. No new matter has been added.

Claims 1-7, 11, and 21-38 have been rejected as obvious over U.S. Patent No. 5,916,596 to Desai *et al.* (Desai) alone or in further view of U.S. Patent No. 6,090,406 to Popescu *et al.* (Popescu). Additionally, all pending claims 1-19 and 21-38 have been rejected as obvious over U.S. Patent No. 4,826,689 to Violanto *et al.* (Violanto) in view of U.S. Patent No. 5,922,355 to Parikh *et al.* (Parikh), or over the combination of Violanto and Parikh in further view of Popescu.

The various bases for the claim rejections are addressed below in the order presented in the official action. Reconsideration of the application as amended is respectfully requested.

CLAIM REJECTIONS – 35 U.S.C. §103

All pending claims have been rejected as variously obvious over Desai, Popescu, Violanto, and/or Parikh. The applicants respectfully traverse the rejections.

As an initial matter, the applicants submit that U.S. Patent Publication No. 2003/0096013, which was cited at page 3 of the action, is not available as a reference against the pending claims under any section of 35 U.S.C. §102 as the subject matter referenced by the examiner is only entitled to a September 17, 2002, filing date, which is subsequent to this application's filing date.

Additionally, in response to the examiner's assertion at page 3 of the official action that room temperature "varies from lab to lab and country to country and does not reflect the actual temperature," the applicants respectfully submit that "room temperature" is a well-known term of art and is a clear indication of a particular temperature range. For example, *The American Heritage® Dictionary of the English Language*, Fourth Edition (2000), defines

room temperature to be an indoor temperature of from 20 to 25°C (68 to 77°F).¹

Accordingly, the “at a temperature below room temperature” limitation recited in all pending claims is entitled to and should be accorded patentable weight.

With respect to the merits of the outstanding rejections, none of the cited documents discloses or suggests “evaporating essentially all of the water immiscible organic solvent by sonicating the system at a temperature below room temperature, thereby decreasing the solubility of the pharmaceutically effective compound in the system and precipitating particles of the compound from the organic phase into the aqueous phase, the particles having an average effective particle size of less than about 2 μm ” as recited by claims 1-24 and 30-34. Similarly, none of the cited documents discloses or suggests “evaporating essentially all of the water immiscible organic solvent by sonicating the emulsion at a temperature below room temperature, thereby decreasing the solubility of the pharmaceutically effective compound in the emulsion and precipitating the compound to form a suspension of submicron sized particles,” as recited by claims 25-29 and 35-38.

For example, Desai makes it clear that sonication is not used to achieve evaporating as claimed. In this regard, Desai states that “[o]ptionally, the organic and/or aqueous phases are *thereafter removed* from the mixture after having been subjected to high shear conditions.” See Desai at column 7, lines 52-54. Clearly then, Desai differentiates between subjecting a mixture to high shear conditions (such as by sonication) and evaporating essentially all of the solvent therefrom. Accordingly, Desai does not suggest *evaporating essentially all of the water immiscible organic solvent by sonicating the system/emulsion at a temperature below room temperature*, as recited by all pending claims.

Popescu does not remedy this deficiency. At best, Example 1 of Popescu discloses sonicating a solution at *elevated temperature* to remove “substantially all ether” therein. In contrast, all pending claims recite *sonicating at a temperature below room temperature*.

Moreover, Popescu sonicates solutions at elevated temperature — not multiphase emulsions, as claimed. Further, Popescu sonicates solutions at elevated temperature to bring the solutions to (substantial) dryness. Accordingly, Popescu does not disclose or suggest using such a technique to precipitate particles of a compound from an organic phase into an aqueous phase, or to form a suspension, as claimed. Still further, a skilled artisan would not be motivated to employ this technique in the method of Desai — for example, because Desai

¹ A copy of this definition is attached hereto as Attachment A.

clearly differentiates between solvent removal and subjecting a mixture to high shear conditions (such as by sonication).

The rejection over the combination of the combination of Violanto and Parikh is not well understood. The examiner appears to be relying upon Popescu in order to sustain this rejection. *See*, for example, the official action dated June 9, 2006, at page 6. Accordingly, the combination of Violanto, Parikh, and Popescu is addressed herein.

Violanto introduces a precipitating liquid into an organic solvent containing a dissolved organic compound in order to form particles. *See* Violanto abstract. No evaporating step is disclosed or contemplated. The disparate teachings of Violanto relative to the claimed invention are considerable, and the applicants respectfully submit that the examiner's reliance on same is misplaced.

Parikh adds nothing further to the analysis and was presumably cited by the examiner for its disclosure of compounds, particle sizes, and surface modifiers. Like Violanto, Parikh fails to disclose or suggest an evaporating step. The fact that some solvent likely evaporates when the mixture of Example 1 is sonicated is irrelevant. Parikh, like the other cited references, fails to disclose or suggest *evaporating essentially all of the water immiscible organic solvent by sonicating the system/emulsion at a temperature below room temperature*, as recited by all claims.

Furthermore, the teachings of Parikh are applicable to solutions — not multiphase emulsions, as claimed. Accordingly, Parikh does not disclose or suggest precipitating particles of a compound from an organic phase into an aqueous phase, or forming a suspension, as claimed.

As discussed above, Popescu sonicates solutions at elevated temperature — not multiphase emulsions as claimed. Further, Popescu sonicates solutions at elevated temperature to bring the solutions to (substantial) dryness. Accordingly, Popescu does not disclose or suggest *evaporating essentially all of the water immiscible organic solvent by sonicating the system/emulsion at a temperature below room temperature* thereby precipitating particles of a compound from an organic phase into an aqueous phase or to form a suspension, as claimed. Moreover, a skilled artisan would not be motivated to combine the sonicating technique disclosed by Popescu with either Violanto or Parikh in view of their silence with respect to an evaporating step. Additionally, Popescu merely discloses sonicating solutions at elevated temperatures, and not below room temperature as claimed.

Because none of the cited documents, whether taken alone or in any combination, discloses or suggests *evaporating essentially all of the water immiscible organic solvent by sonicating the system/emulsion at a temperature below room temperature*, as recited by all claims, the applicants submit that a *prima facie* case of obviousness has not been established, and the rejections of all pending claims should be withdrawn.

CONCLUSION

It is respectfully submitted that this application is now in condition for allowance. Should the examiner wish to discuss the foregoing, or any matter of form or procedure in an effort to advance this application to allowance, he is respectfully invited to contact the undersigned attorney at the indicated telephone number.

Respectfully submitted,

MARSHALL, GERSTEIN & BORUN LLP



Andrew M. Lawrence, Reg. No. 46,130
Attorney for Applicants
6300 Sears Tower
233 S. Wacker Drive
Chicago, Illinois 60606-6357
(312) 474-6300

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The American Heritage® Dictionary of the English Language: Fourth Edition. 2000.

room temperature

NOUN: *abbr. RT* An indoor temperature of from 20 to 25°C (68 to 77°F).

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Attachment "A"